Sub ( Sub )

by adding a pharmaceutically or cosmetically active substance to the carrier to form a formulation for a topical cream or lotion formulation; wherein the galactolipid material is present in the formulation in an amount to prolong the local effect of the pharmaceutically or cosmetically active substance when the formulation is applied; and

- c. topically applying the topical cream or lotion formulation; and
- d. wherein the galactolipid material is present in the formulation in an amount to prolong the local effect of the pharmaceutically or cosmetically active substance when the formulation is applied.

## REMARKS

Responsive to the Final Office Action, reconsideration of the reasons for the continued rejection of the claims is respectfully solicited especially in light of the further amendment to claim 1. Claim 1 has been amended to more definitely define that the present method is directed to application of a pharmaceutically or cosmetically active substance to a topical area wherein a formulation is created utilizing oil-in-water emulsion carrier, including an oily non-polar lipid material, an aqueous phase and a galactolipid material, blended with a pharmaceutically or cosmetically active substance. The methodology requires the topical application of

the topical cream or lotion formulation wherein the galactolipid is present in the formulation in a amount to prolong the local effect of the active substance of the topically applied cream or lotion. Such a topical application of a formulation, including a galactolipid material sufficient to prolong the local effect of the active substance of the pharmaceutical or cosmetic material, is not disclosed nor suggested by the prior art reference relied upon by the Examiner to Carlsson et al.

• •

Applicants reiterate the remarks set forth in the response to the initial office action. As pointed out by the Examiner in the final office action at page 2 and extending to line 3, the prior art discloses only that "an intrinsic beneficial feature of the galactolipids is the galactose units comprising the polar headgroup in each lipid molecule, which may sterically stabilize the emulsion droplets, and thus provide for a prolonged life-span when injected into the blood steam." It is noted that this quote from page 5, line 1 through 5 of the references is directed to an injection of emulsion droplets into the blood stream, and there is no suggestion of prolonging a local topical effect of a pharmaceutically or cosmetically active compound when applied topically.

It is respectfully submitted that the suggested teachings of the reference would not be considered by one of ordinary skill in the art for application to prolong a local effect of a topically applied active substance by providing sufficient galactolipid

materials to enhance and provide for the prolonged effect, as is disclosed and taught by the present invention.

Further, the Examiner has maintained the 103 rejection and stated the applicants do not provide specific arguments regarding the rejection. It should be noted, however, that applicants have directed their remarks to the primary reference to Carlsson et al. It is respectfully submitted that this reference does not provide a sufficient nexus to the teachings of the present invention as claimed in which to support the combination rejection with the secondary reference to Yamada et al., US Patent 5,885,978. Therefore, regardless of what may be taught in Yamada, the combination cannot teach the inventive characteristics of the present invention for reasons set forth above with respect to Carlsson et al.

In view of the foregoing, reconsideration and withdrawal of the grounds for rejection and favorable consideration and allowance of the claims as amended is respectfully solicited.

Respectfully submitted,

Ralph A. Dowell

Registration No. 26,868

Date: July 16, 2002

DOWELL & DOWELL, P.C. Suite 309 1215 Jefferson Davis Highway Arlington, Virginia 22202 Telephone (703) 415-2555 VERSION WITH MARKINGS TO SHOW CHANGES MADE

- 1. (Twice Amended) A method of prolonging a local effect of a pharmaceutically or cosmetically active substance when such substance is used in a topical cream or lotion, the method comprising:
- a. providing an oil-in-water emulsion carrier including an oily non-polar lipid material, an aqueous phase and a galactolipid material as an emulsifier;
- b. adding a pharmaceutically or cosmetically active substance to the carrier to form a formulation for a topical cream or lotion formulation; [and] wherein the galactolipid material is present in the formulation in an amount to prolong the local effect of the pharmaceutically or cosmetically active substance when the formulation is applied;
- c. [wherein the galactolipid material is present in the formulation for a topical cream or lotion in an amount to prolong a local effect of the active substance when the topical cream or lotion is topically applied] topically applying the topical cream or lotion formulation; and
- d. wherein the galactolipid material is present in the formulation in an amount to prolong the local effect of the pharmaceutically or cosmetically active substance when the formulation is applied.